

AUG 09 2002

K021579
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**510(k) PREMARKET NOTIFICATION
SUMMARY OF SAFETY AND EFFECTIVENESS
Magly 4.0 and 5.5mm Locking Screws**

Submission Information

**Name and Address of the Sponsor
Of the 510(k) Submission:**

Magly Orthopedics, LLC
14241 NE Woodinville-Duvall Road, #415
Woodinville, Washington 98072
425.489.2057 Phone
425.482.0147 Fax

Contact Person:

Dave Stinson

Date Summary Prepared:

April 9, 2002

Device Identification

Proprietary Name:

Magly 4.0 and 5.5mm Locking Screws

Common Name:

4.0mm Locking Screw, Fully Threaded
5.5mm Locking Screw, Fully Threaded

Classification:

Screw, Fixation, Bone
21 CFR §888.3040

Predicate Device Identification

The Magly 4.0 and 5.5mm Locking Screws are substantially equivalent to that of the predicate Synthes 4.0 and 5.0mm Locking Screws. The Magly 4.0 and 5.5mm Locking Screws are similar to the listed predicate device in design, function, materials used, and indications for use.

Device Description

The screws are fully threaded from the distal tip to approximately 1mm to 2mm under the head. The distal end will embody a spherical shape at the tip and four cutting flutes used for tapping the thread profile.

The locking screws will be available in 2mm incremental lengths, measured from under the head to the distal tip, the 4.0mm from 16mm-80mm and the 5.5mm from 20mm-120mm.

Magly 4.0 and 5.5mm Locking Screws are manufactured from titanium alloy.

Intended Use of the Device

Magly 4.0 and 5.5mm Locking screws are used for the interlocking of APEX Intramedullary Femoral and Tibial Nails.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 09 2002

Mr. Dave Stinson
Partner
Magly Orthopedics, LLC
14241 NE Woodinville-Duvall Road, #415
Woodinville, Washington 98072

Re: K021579

Trade/Device Name: Magly 4.0 and 5.5mm Locking Screws
Regulation Number: 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: April 12, 2002
Received: May 14, 2002

Dear Mr. Stinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

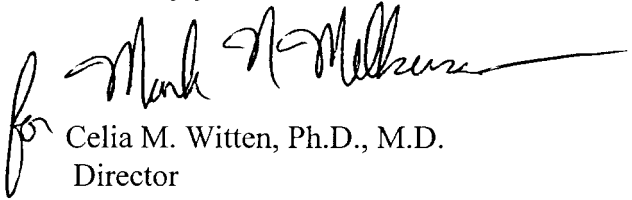
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 -- Mr. Dave Stinson

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

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510(k) Number: K021579

Device Name: Magly 4.0 and 5.5mm Locking Screws

Indication(s) for Use:

- Magly 4.0 and 5.5mm Locking screws are used for the interlocking of APEX Intramedullary Femoral and Tibial Nails

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____

for Mark H. Miller
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

(Optional Format 1-2-96)

510(k) Number K021579

Magly Orthopedics, LLC
Magly 4.0 and 5.5mm Locking Screws